

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Subchapter R

[OPTS-62094; FRL-3797-9]

Comprehensive Review of Lead in the Environment under TSCA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking (ANPR).

SUMMARY: EPA is exploring the desirability and feasibility of various approaches under the Toxic Substances Control Act (TSCA) to significantly reduce any unreasonable risks to human health and the environment from exposures to lead (Pb) as part of an Agency-wide initiative to control unacceptable Pb risks. For purposes of this ANPR, Pb will refer to elemental Pb and Pb-containing compounds. This regulatory investigation will explore use of TSCA section 6 to determine if uses of Pb present unreasonable risks. To that end, the Office of Toxic Substances intends to: (1) Control existing or new uses of Pb which pose an unreasonable risk of injury to health or the environment; and (2) explore the desirability and feasibility of discouraging overall consumption of Pb in general, while encouraging environmentally sound recycling of Pb products. The regulatory investigation will evaluate specific market approaches, such as fees and marketable permits where appropriate, which may offer more efficient ways of achieving the same goals.

EPA is issuing this ANPR to invite comment and to request information on the issues outlined in this document in order to determine if the risks are unreasonable. Discussion of issues relating to abatement of Pb already in the environment is beyond the scope of this document. However, these issues, along with the activities included in this ANPR and other Agency-wide activities, are discussed at length in the Agency's Strategy to Reduce Lead Exposures. To receive more information on the Agency Strategy or to receive a copy of the Strategy document, contact the office listed under "FOR FURTHER INFORMATION CONTACT."

DATES: Written comments must be received by the Agency no later than August 12, 1991.

ADDRESSES: Comments should be submitted in triplicate to: The TSCA Docket Office (TS-793), Office of Toxic Substances, Environmental Protection Agency, rm. NE-G004, 401 M St., SW.,

Washington, DC 20460, Attention: OPTS-62094.

Comments containing confidential business information (CBI) should be submitted in triplicate to: The Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, rm. E-105, 401 M St., SW., Washington, DC 20460, Attention: OPTS-62094. A sanitized copy of confidential comments must be provided in triplicate to the TSCA Public Docket Office.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division, Office of Toxic Substances, Environmental Protection Agency, rm. E-543, 401 M St., SW., Washington, DC 20460, 202/554-1404, TDD: 202/554-0551.

SUPPLEMENTARY INFORMATION: EPA is considering proposing rules to control Pb exposures, if unreasonable risks are present, under TSCA to:

1. Limit or, if appropriate, ban new or existing uses of Pb in specific products which present an unreasonable risk of injury to health or the environment.

2. Limit or, if appropriate, severely restrict overall Pb mining, importation, manufacturing, processing and distribution.

3. Limit or prohibit methods of disposal other than recycling for certain Pb products.

Rules based on (or using) economic incentives (as well as command and control rules) may achieve the goals of all the regulatory approaches mentioned above. Some examples of economic incentive approaches include a marketable permit system involving allocation by EPA (or by government-run auction or sale) of rights to produce or use Pb or fees on such production or use. EPA invites comment generally on the feasibility and desirability of promulgating economic incentive based rules to reduce the unreasonable risks posed by Pb in the environment. In addition, EPA invites comments on methods of integrating TSCA with other statutory authorities to achieve the goal of controlling unreasonable risks.

I. Regulatory Framework

This document announces initiation of a regulatory investigation of Pb under TSCA, and solicits comment on several regulatory approaches under consideration. The legal framework within which these approaches will be considered is described below.

TSCA conveys authority to regulate chemical substances. To regulate under section 8, TSCA requires a finding that there is a reasonable basis to conclude that activities involving the chemical

substance, in this case Pb, present or will present an unreasonable risk of injury to health or the environment. The finding of unreasonable risk reflects a general cost/benefit analysis, in which the adverse health and environmental effects resulting from exposure to a substance are found to outweigh its overall societal benefits. Finding a risk "unreasonable" would involve weighing the health and environmental benefits of reducing specific Pb exposures—e.g., by limiting, or, if appropriate, banning particular Pb uses or products—against the societal costs of substituting other products or processes. EPA will also consider the desirability of overall reductions in Pb production and use if the Agency determines that the introduction of Pb into the environment, in general, presents unreasonable risks.

The regulatory initiatives discussed in this notice will be coordinated, within the framework of an overall Agency strategy to reduce unacceptable Pb exposures, with several other ongoing EPA research and control activities. These other activities include reviews of existing standards regarding Pb exposure under the Clean Air Act, the Clean Water Act, the Safe Drinking Water Act, the Resource Conservation and Recovery Act, and the Comprehensive Environmental Response, Compensation and Liability Act. Potential actions include revision of the national primary drinking water regulations for Pb; an ANPR to solicit comments on options to encourage recycling; review of the New Source Performance Standard for secondary smelters; issuance of a Notice of Proposed Rulemaking on the National Ambient Air Quality Standards for Pb; promulgation of regulations for the use/disposal of sewage sludge; research to evaluate critical Pb issues such as the impact of abating Pb-contaminated soil on children's blood lead (PbB) levels; and a joint Agency effort to develop a program to reduce unacceptable exposures to Pb.

II. Background

Over the last two decades EPA has taken a number of actions to control exposure to Pb because of its toxic properties. Most notable of these actions has been the virtual removal of Pb from gasoline. As a result of this action, along with the voluntary phase-out of Pb solder in food cans by domestic manufacturers, the average PbB level in U.S. children has declined from about 17 micrograms per deciliter ($\mu\text{g}/\text{dl}$) to between approximately 4 and 8 $\mu\text{g}/\text{dl}$ over the past decade.

A. Human Health Effects

Exposure to Pb can produce a spectrum of human health effects across a wide range of exposure levels. Recent studies indicate that these toxic effects may occur at exposure levels considerably lower than previously recognized. PbB is the most common index of Pb exposure. The current PbB level of concern may be reduced as more is learned about Pb toxicity.

Young children and fetuses are especially vulnerable to Pb. High PbB levels (> 40–60 in $\mu\text{g}/\text{dl}$) in children are associated with anemia, mental retardation, encephalopathy, and at extremely high levels (> 100 $\mu\text{g}/\text{dl}$), even death. There is also concern that high Pb exposures might play a role in spontaneous abortions. Even at low doses, where impacts are more subtle, Pb exposure has been associated with a variety of effects including slight increases in blood pressure in adults, and subtle deficits in attention span, hearing, learning abilities, and heme synthesis and vitamin D metabolism in children. Pb exposure is also associated with reproductive effects in men and women, and with decreased birth weight and decreased physical and mental development in neonates. Recent studies suggest that even children with subclinical effects (i.e., no obvious symptoms) might suffer significant and persistent changes.

While Federal government interest in Pb poisoning has focused on children, there is substantial evidence that exposed adults also face health risks. Since Pb is stored in bone, it may be mobilized during periods of stress or greater metabolic demands for calcium such as pregnancy and in individuals suffering from osteoporosis.

B. Environmental Effects

Pb is one of the most common toxicants in large and small animals. Pb poisoning is the most frequently diagnosed toxicological problem in veterinary medicine; its occurrence has been reported in all domestic species and in several species of zoo animals. Pb poisoning has also affected every major species of waterfowl in North America and has been reported in many birds elsewhere in the world. Sources of these exposures have typically included Pb wastes, Pb paint, spent Pb shot, fishing sinkers, and contaminated forage near Pb smelters.

Laboratory and field data show that at high concentrations, Pb can affect certain plants and inhibit photosynthesis, reduce growth, and alter species composition. Other studies also indicate that high Pb concentrations

alter the composition of soil microbial communities and inhibit invertebrate activity resulting in delayed decomposition of organic matter, reduced nutrient supply, and altered soil properties, such as lower organic content.

Pb is toxic to all phyta of aquatic biota. Water Pb concentrations as low as 19 to 30 $\mu\text{g}/\text{l}$ have been associated with increased mortality and impaired reproduction in aquatic invertebrates. Vertebrates (i.e., fish) appear even more sensitive. Studies have shown that freshwater vertebrates and invertebrates are more sensitive to Pb in soft than in hard water.

C. Current Uses of Pb

Some uses of Pb have the potential to be replaced by substitutes for a reasonable cost. Other uses, such as Pb-acid batteries and radiation shielding, may not be easily replaced. Given Pb's toxicity and persistence, EPA plans a comprehensive life cycle review of all uses of Pb to identify further steps which might be taken to reduce any unreasonable human and environmental risks. EPA requests information on the range of specific current uses of Pb, the amounts of Pb involved in each of these uses, and the potential risks associated with the uses and the cost of substitutes. Specific types of information requested are listed under Unit III.

III. Summary of TSCA Pb Pollution Prevention Regulatory Plan

This summary includes a description of activities the Agency is currently exploring under TSCA section 6 to reduce unreasonable risks from Pb uses, with the exception that Pb-acid battery recycling is not discussed here. The battery initiative was described in a separate **Federal Register** notice (55 FR 52864, December 24, 1990) and is currently the subject of an ongoing regulatory negotiation. Questions on the battery recycling regulatory negotiation should be addressed to Nancy Laurson, U.S. EPA (TS-794), 401 M St., SW., Washington, DC 20460, telephone (202) 382-3945.

A. Phase-out of Current Uses of Pb Posing Unreasonable Risks

Initiative. EPA will initiate a regulatory investigation under TSCA section 6(a) to determine whether any of several specific current uses of Pb pose unreasonable risks. Specific uses or products tentatively identified for consideration include, but are not necessarily limited to: brass and bronze plumbing fittings and fixtures (e.g., faucets), Pb solder used to join pipes carrying drinking water, and Pb in

nonresidential paint (e.g. for bridges, water towers, and roads).

Rationale. Several current uses of Pb have the potential to generate high human or environmental risk during or after use. For instance, new brass plumbing fixtures and Pb solder used to join pipes carrying drinking water can be major sources of Pb contamination of drinking water. It is also believed that Pb solder, banned from use in potable water supplies in a 1986 amendment to the Safe Drinking Water Act, is still being used by a number of professional plumbers and "do-it-yourselfers." Removal of Pb-based paint from bridges and similar structures can contribute to high human and environmental risks. EPA intends to investigate such uses, considering the benefits of each product relative to the risk, in order to determine if they pose an unreasonable risk, and, if necessary, control their use under TSCA.

EPA requests comments and information pertinent to brass and bronze plumbing fittings and fixtures, illegally installed Pb solder, Pb in nonresidential paint, and other high exposures, including: Actual exposures associated with these Pb uses and products, typical and high end PbB levels as well as exposure histories in workers and others exposed in each of the major use categories, environmental and ecosystem effects, annual volume of Pb consumption for each use, benefits of Pb in each use, available substitutes for Pb for each use, comparative health and environmental effects of the substitutes, the effectiveness of the current ban on Pb solder in drinking water systems and mechanisms to improve it, and other high exposure uses and products.

B. General Pb Reduction

Initiative. EPA is exploring, after considering the range of lead products, the possibility of using TSCA to limit or reduce general Pb production if the Agency determines that use of Pb presents an unreasonable risk of injury to health and the environment. Possible TSCA section 6(a) rules to achieve this end, based on a balancing of the benefits to society of various reductions against their associated costs, include: (1) Limitations or, if appropriate, bans on certain Pb uses and/or categories of uses; (2) restrictions on general consumption of Pb; and (3) economic incentives for reducing Pb use.

Under TSCA, the basis for any or all of these actions would be that continued environmental loading of Pb presents an unreasonable risk of injury to health and the environment. The finding of unreasonable risk reflects cost/benefit

analysis in which EPA would be required to demonstrate that benefits to society of the exposure reduction actions exceed the cost of such controls. The Agency requests comments on the level (e.g., lifecycle, product category, or product) it should use for the cost-benefit analysis.

EPA also requests comment on the feasibility of the following approaches to reduce unreasonable risks from overall Pb production and use, which include but are not limited to the following:

1. EPA could focus on specific uses, or categories of uses, of Pb. This approach could be similar to the approach used for the phase-out of current Pb uses described above, or additional criteria could be used. EPA requests comment on the criteria which should be used in selecting uses for reductions, on examples of uses which might satisfy these criteria, and information on exposure and risk associated with various products and/or product categories, and the cost and risk of substitutes.

2. EPA could focus on reducing the use of Pb through market incentives. This approach could result in less toxic materials being substituted for Pb in products where those substitutions seem most feasible, without further EPA intervention. EPA requests comment on the feasibility of this approach, including whether these market incentives should focus only on virgin Pb or on all Pb, ways for EPA to estimate potential benefits (reductions in risk) likely to be achieved through this approach, whether this approach is likely to address the uses of greatest concern and, if those uses are not adequately addressed, ways to modify this approach so that the uses of greatest concern will be addressed.

3. EPA could focus on mandating recycling. EPA requests comment on the feasibility of this approach for uses other than batteries, including the questions noted below.

To further help EPA decide whether or not to limit production, consumption or use of Pb that pose unreasonable risks, the Agency requests comment and information on the following:

1. *Reducing the volume of Pb introduced into the environment.* i. The nature and strength of the relationship between general consumption of Pb under current and anticipated future patterns of usage and current and/or future human and environmental exposure.

ii. The effect of restricting the amount of virgin Pb refined and introduced into

the environment on other metals which are coproduced with Pb.

2. *Current and future Pb use and consumption posing unreasonable risks.*

i. The identity of current Pb uses, including specific products, and the amount of Pb used in specific products.

ii. The availability of feasible substitutes, and the cost increases and risks associated with such substitutes.

iii. Ongoing or planned research to identify substitutes for Pb in products.

3. *Recycling Pb.* i. The desirability of regulations to encourage recycling of Pb products in addition to Pb-acid batteries.

ii. The effectiveness of restricting production of virgin Pb as a means to encourage recycling.

iii. The relative effects of restricting virgin Pb versus restricting consumption of all Pb as a means of encouraging recycling.

4. *Product stewardship.* i. Identification of the life cycle of Pb (including Pb-containing products).

ii. Current industry procedures and practices to minimize exposure to Pb for each major use, from mining to disposal.

iii. Effectiveness of the above procedures and practices, including weaknesses either because of the inherent weakness of the practice or because of significant potential for people to fail to follow procedures.

iv. The effectiveness of various waste disposal methods for controlling unreasonable risks for discarded Pb products.

v. The extent/rate to which natural processes can be expected to reduce human or environmental exposure.

vi. Amount of Pb and risk, by product category, disposed of in municipal solid waste landfills.

5. *Means to reduce any unreasonable risks from Pb uses.* For any of the possible goals named above (regarding specific products or overall Pb use), identify:

i. Market mechanisms or economic incentives that could be applied to achieve them.

ii. Regulatory mechanisms that could be implemented to achieve them.

iii. Pollution prevention approaches.

iv. Methods of dealing with imports into the U.S. and exports of Pb and Pb-containing products under any of the above approaches to reducing unreasonable risks from Pb uses.

IV. Rulemaking Record

EPA has established a record for this advanced notice of proposed rulemaking (docket control number OPTS-62094). A public version of the record, without any

confidential business information, is available in the TSCA Public Docket Office, from 8 a.m. to noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays. The TSCA Public Docket Office is located in Room NE-G004, 401 M St., SW., Washington, DC.

The following supporting documentation for this ANPR is available upon request from the address listed above:

1. Davis, J. Michael and David J. Svendsgaard, "Lead and Child Development," *Nature*, 329, (September 24, 1987): 297-300.

2. USDHHS, PHS, *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*, February 1991.

3. USDHHS, PHS, Agency for Toxic Substances and Disease Registry (ATSDR), *The Nature and Extent of Lead Poisoning in Children in the United States: A Report to Congress*, July 1988.

4. USEPA, *Strategy for Reducing Lead Exposures*, February 21, 1991.

5. USEPA, OAQPS, AQMD, *Review of the National Ambient Air Quality Standards for Lead: Assessment of Scientific and Technical Information*, OAQPS Staff Paper, June 1989.

6. USEPA, ORD, OHEA, ECAO, *Air Quality Criteria for Lead: Volume I*, EPA/600/8-83/028aF, June 1986.

7. USEPA, ORD, OHEA, ECAO, *Air Quality Criteria for Lead, Volume II*, EPA/600/8-83/028bF, June 1986.

8. USEPA, ORD, OHEA, ECAO, *Air Quality Criteria for Lead, Volume III*, EPA/600/8-83/028cF, June 1986.

9. USEPA, ORD, OHEA, ECAO, *Air Quality Criteria for Lead, Volume IV*, EPA-600/8-83/028dF, June 1986.

10. USEPA, ORD, OHEA, *Supplement to the 1986 EPA Air Quality Criteria for Lead - Volume I Addendum*, EPA/600/8-89/049F, August 1990.

11. USEPA, ORD, OHEA, *Evaluation of the Potential Carcinogenicity of Lead and Lead Compounds: In Support of Reportable Quantity Adjustments Pursuant to CERCLA Section 102, Review Draft*, EPA/600/8-89/045A, March 1989.

Dated: May 3, 1991.

Linda J. Fisher,
Assistant Administrator for Pesticides and Toxic Substances.

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